UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,570	06/19/2002	Iain Alasdair Donaldson	078883-0139	9774

22428 7590 07/14/2005

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/009,570	DONALDSON ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,25 and 27-48* is/are pending in the application.

4a) Of the above claim(s) *6,25 and 30-48* is/are withdrawn from consideration.

5)☐ Claim(s) *3 and 4* is/are allowed.

6)☒ Claim(s) *1-2, 5, 7-23, 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed March 22, 2005 has been entered.

Claims 24 and 26 are cancelled.

Claims 27-48 are newly added.

Claims 1-23, 25 and 27-48 are pending.

Claims 6 and 25 are withdrawn

Claims 1-5 and 7-23 are currently amended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claims 30-48 are directed to inventions that are independent or distinct from the invention originally claimed and elected for the following reasons: the invention originally claimed and elected is a promoter comprising a nucleotide sequence corresponding to that shown as SEQ ID NO:1, sequence corresponding to that shown as SEQ ID NO:1 and a construct and vector comprising said promoter, whereas newly submitted claims 30-48 are directed to a construct comprising a pGUSNOSt expression vector and a Rsus3 promoter operably linked to a uidA gene, a construct comprising a tandem repeat Rsus3 promoter operably linked to a uidA gene, a construct comprising a Rsus3 promoter operably linked to a luciferase gene, and a construct comprising a NOS promoter operably linked to a luciferase gene. Newly submitted claims 30-48 are directed to constructs comprising different structural components

than those recited in the constructs presented in the originally elected claims, which components would require an additional search.

Since applicant has received an action on the merits for the originally claimed and elected invention, claims 30-48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 1-23, 25 and 27-29 are examined.

Claim Objections

Claim 20 remains objected to for the reasons of record set forth in the office action mailed December 14, 2004.

Applicant's arguments filed March 22, 2005 have been fully considered but they are not persuasive.

Applicant maintains that the objection is overcome by the amendment of the claims. (reply page 11)

The objection is withdrawn with respect to claims 9, 14, 21, and 22, but maintained with respect to claim 20, as claim 20 continues to recite the acronym "POI" without recitation of what it designates.

Claim Rejections - 35 USC § 112

Claims 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. This is a new matter rejection. Claims 13-14 require "a nucleotide sequence with at least 75% homology to SEQ ID NO:5", which does not find support in the specification as filed and thus constitutes new matter.

Claims 1-2, 5, 7-22 and 26 remain rejected, and claims 28-29 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed December 14, 2004. This is a written description rejection.

Applicant's arguments filed March 22, 2005 have been fully considered but they are not persuasive.

Applicants point out that they have amended the claims to delete the recitation of the phrase "variant, homologue, fragment or derivative thereof", and that, as amended, the claims recite a "nucleotide sequence with at least 75% homology to SEQ ID No. 1". Applicants maintain that the sequences are thus structurally defined by an easily quantifiable value. Applicants also point out that that the specification provides a number of specific examples of nucleotide sequences with at least 75% homology to SEQ ID No. 1, and that, in addition, the specification describes ways of obtaining the claimed genus of species, including tests for function. Applicants additionally maintain that the claims also describe the claimed genus in terms of function, and specifically point out that the claims do not cover any sequence meeting the structural requirements but instead cover promoters meeting the structural requirements.

Applicants further maintain that when a claimed genus of polynucleotides is defined in terms of both structure and function, a specific recitation of each species is not required, and that the art has developed to such a point that such an extensive description is not necessary to demonstrate possession. (reply pages 11-12)

The Examiner maintains that the claimed invention is not adequately described, as the description of a single isolated promoter polynucleotide obtained from the rice sucrose synthase 3 gene that comprises SEQ ID NO:1, and twelve different truncations of SEQ ID NO:1 that function to express a GUS reporter gene in guar endosperm, is not representative of a genus that encompasses isolated promoter polynucleotides obtained from any unspecified source wherein the polynucleotides comprise a nucleotide sequence with at least 75% homology to SEQ ID NO:1. Additionally, that the sequences are structurally defined by an easily quantifiable value does not satisfy the written description requirement, as not all polynucleotides that comprise a nucleotide sequence with at least 75% homology to SEQ ID NO:1 would exhibit promoter function. Further, with respect to the specification describing ways of obtaining the claimed genus of species, including tests for function, such a disclosure does not satisfy the written description requirement, as the description of a sequence is not dependent on whether the specification provides an enabling disclosure. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993):

> An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.

See also *University of California v. Eli Lilly*, 43 USPQ 2d 1398, 1405 (Fed. Cir. 1997):

> The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for

> obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself.

The Examiner also maintains that the recitation of structure (nucleotide sequence with at least 75% homology to SEQ ID NO:1) and function (promoter) in the claims does is not sufficient to satisfy the written description requirement. Rather, the description of a representative number of species of nucleotide sequences with at least 75% homology to SEQ ID NO:1 that have promoter function is necessary to satisfy the written description requirement.

Claims 1-2, 5, 7-22 and 26 remain rejected, and claims 23, 28 and 29 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a promoter comprising or having a nucleotide sequence corresponding to that shown as SEQ ID No. 1 and the disclosed functional fragments of SEQ ID NO:1, does not reasonably provide enablement for undisclosed variants, homologues, fragments or derivatives of SEQ ID NO:1, or for other promoters obtained from other plant species of the genus Oryza, or for a promoter according to claim 1 that is linked to the sequence presented as SEQ ID No. 2, or a variant, homologue, derivative or fragment thereof, or for a promoter according to claim 1 wherein the promoter comprises one or more of the identified sequences presented in Table 1 or a variant, homologue or fragment thereof, or for a promoter according to claim 1 that is linked to the sequence

presented as SEQ ID No. 5 or a variant, homologue, derivative or fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed December 14, 2004.

Applicant's arguments filed March 22, 2005 have been fully considered but they are not persuasive.

Applicants maintain that the specification contains guidance to allow one of skill in the art to practice the claimed invention without undue experimentation, as the specification discloses numerous specific examples of how to make and use the claimed subject matter. Applicants also maintain that the specification does in fact disclose ways of obtaining nonexemplified species of the claimed genus, including tests for function. Applicants also point out that the specification also extensively describes transformation and organisms to be transformed., which supplements the specific examples disclosed and the general knowledge of one of skill in the art. In response to the examiner's allegation that the state of the art is uncertain because promoter function cannot be predicted based on homology alone, Applicants point out that the state of the art is such that homologs can be readily produced. Applicants also point out that methods exist, such as those described in the specification, to allow one of ordinary skill in the art to routinely screen sequences for activity. Applicants maintain that methods of obtaining promoters related to the specifically recited promoters are routine and largely automated, and that the methods of screening homologous sequences for promoter activity are also routine and often at least partially automated, such that even if complex experimentation is required, the experimentation is not necessarily undue. (reply pages 13-14)

The Examiner maintains that the full scope of the claimed invention is not enabled. The outstanding rejection was not predicated on the failure to provide guidance with respect to cloning and screening techniques that are known to and within the abilities of one skilled in the art. The outstanding rejection was predicated on the failure to provide guidance with respect to the which sequences to clone and screen. Such guidance is necessary because it is unpredictable whether variants of SEQ ID NO:1 would function as a promoter, or as an endosperm-preferred promoter, because basal and tissue-specific promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the promoter polynucleotide, which nucleotides and motifs may not be present in variants of SEQ ID NO:1. The unpredictability of variant polynucleotides functioning as promoters is not an allegation; it is due to the known physical properties of promoter polynucleotides (i.e. the requirement for the presence of specific key nucleotides and regulatory regions for basal or tissue-specific promoter function). Absent such guidance one skilled in the art would have to isolate from undisclosed sources and/or synthesize variant nucleic acid sequences, and then test each sequence and/or sequence combination for basal and endosperm-preferred promoter function, in order to discriminate between operative and nonoperative sequences encompassed by the claims. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27 is rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Claims 27 as written does not sufficiently distinguish over nucleic acids as they exist naturally because the claim does not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claim should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Allowable Subject Matter

Claims 3 and 4 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Claims 1-2, 5, 7-23 and 27-29 are rejected.

Claims 3 and 4 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC

Cynthia Collins
7/8/05